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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,471	10/25/2001	Mehran M. Khodadoust	50200/002003	6131

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,471

Applicant(s)

KHODADOUST, MEHRAN M.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a method for selecting cells using a reporter that is activated upon stimulation, classified in class 435, subclass 6.
- II. Claims 12-15, drawn to a method for selecting cells using a transactivator polypeptide that is activated upon stimulation, classified in class 435, subclass 6.
- III. Claims 16-25, drawn to a method for selecting cells using a reporter that is inactivated upon stimulation, classified in class 435, subclass 6.
- IV. Claims 26-31, drawn to a method for selecting cells using a transactivator polypeptide that is inactivated upon stimulation, classified in class 435, subclass 6.
- V. Claims 32-36, drawn to a method for identifying a nucleic acid using a two-vector system, classified in class 435, subclass 6.
- VI. Claims 37-43, drawn to a method for identifying a nucleic acid using a three vector system, where the reporter gene is located in the second vector along with a recombinase signal sequence and a transactivator polypeptide, classified in class 435, subclass 6.
- VII. Claims 44-50, drawn to a method for identifying a nucleic acid using a three-vector system, where the second vector has a recombinase signal sequence and a transactivator polypeptide but no reporter gene, classified in class 435, subclass 6.

- VIII. Claim 51, drawn to a method for treating/preventing/ stabilizing a disease using a reporter gene to select a compound to be used in the treatment method, classified in class 424, subclass 9.1.
- IX. Claim 52, drawn to a method for treating/preventing/ stabilizing a disease using a transactivator polypeptide to select a compound to be used in the treatment method, classified in class 424, subclass 9.2.
- X. Claims 53-68, drawn to a nucleic acid, vectors containing the nucleic acid and host cells containing the vectors, classified in class 536, subclass 23.1.
- XI. Claims 69-71, drawn to a method for screening compounds as stimulatory agents, classified in class 435, subclass 6.
- XII. Claims 72-74, drawn to a method for screening compounds as regulatory element modulating agents, classified in class 435, subclass 6.
- XIII. Claim 75, drawn to a method for screening compounds as DNA damaging agents, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects and are not disclosed as capable of being used together.

Specifically, Invention I is directed to an outcome where a reporter gene is activated, Invention II is directed to an outcome where a transactivator polypeptides is activated, Invention III is

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directed to an outcome where a reporter gene is inactivated and Invention IV is directed to an outcome where a transactivator polypeptides is inactivated; each of these outcomes is distinct from the other. Therefore, each of the methods has a different outcome, and thus a different effect. As a result, these inventions are patentably distinct from each other.

Inventions V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and modes of operation, and are not disclosed as capable of being used together. Specifically, Invention V uses only a two vector system whereas both Inventions VI and VII use three vector systems, each of which is structurally different from the other (Invention VI has both a reporter and transactivator on the second vector, whereas Invention VII has only a transactivator on the second vector). Thus, each of the methods uses structurally different vectors, each with a different function. Furthermore, because these inventions each use functionally different vector systems, the methods require different methods steps and therefore different modes of operation. AS a result, inventions V-VII are patentably distinct.

Inventions I-IV and V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects and are not disclosed as capable of being used

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together. Specifically, Inventions I-IV are each directed to methods of selecting cells having a specific response to a stimulatory agent whereas Inventions V-VII are each directed to a different method of identifying nucleic acids which modulate the activity of a regulatory element. Because each of these groups of inventions is directed to different outcomes, the different inventions have different effects and are therefore patentably distinct.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and are not disclosed as capable of being used together. Specifically, the different methods require different steps (Invention VIII identifies the compound to be used in the treatment by its ability to activate a reporter, whereas Invention IX identifies the compound to be used in the treatment by its ability to activate a transactivator) in order to practice the invention. Because these inventions make use of different method steps, the inventions have different modes of operation and are therefore patentably distinct.

Inventions VIII-IX and I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different outcomes and are not disclosed as capable of being used together. Specifically, Inventions VIII-IX are drawn to methods of treating a disease, whereas Inventions I-IV are drawn to the selection of cells having a specific response and Inventions V-

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VII are drawn to the identification of nucleic acids. Because these groups of inventions each have different outcomes, the groups of inventions are patentably distinct as having different effects.

Inventions X and I-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids, vectors and host cells can be used in any one of the patentably distinct methods set forth in the methods set forth in the different groups of Inventions I-IV (methods of selecting cells), V-VII (methods of identifying nucleic acids) or VIII-IX (methods of treatment).

Inventions XI-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different outcomes and are not disclosed as capable of being used together. Specifically, Invention XI is drawn to a method of identifying a stimulatory compound, Invention XII is drawn to a method of identifying a compound that modulates a regulatory element and Invention XIII is drawn to a method of identifying a DNA damaging agent. Each of these methods results in a different outcome, and therefore each Invention has a different effect. Furthermore, a different parameter must be monitored in each

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invention to successfully identify a candidate compound, thus the methods require different method steps and thus have different modes of operation. As a result, each invention is patentably distinct from the other.

Inventions XI-XIII and I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects and are not disclosed as capable of being used together. Specifically, Inventions XI-XIII are directed to the identification of compounds, whereas Inventions I-IV (methods of selecting cells), Inventions V-VII (methods of identifying nucleic acids) and Inventions VIII-IX (methods of treating a disease) are drawn to methods with distinct outcomes. As a result of the methods having distinct outcomes, each group of inventions have different effects and are therefore patentably distinct.

Inventions XI-XIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids, vectors and host cells of Invention X can be used any one of the patentably distinct methods set forth in the methods set forth in the different groups of Inventions I-IV (methods of selecting cells), V-VII (methods of identifying nucleic acids), VIII-IX (methods of treatment) or XI-XIII (methods of identifying compounds).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

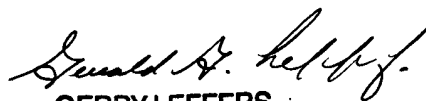
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
AU 1636


GERRY LEFFERS
PRIMARY EXAMINER